

## Environmental Protection Agency

## § 158.2081

or LC<sub>50</sub> determined in the aquatic nontarget organism testing.

11. Required if either of the following criteria are met:

i. Environmental fate characteristics indicate that the estimated concentration of the pesticide in the terrestrial environment is >0.20 the avian dietary LC<sub>50</sub> or equal to >0.20 the avian oral single dose LD<sub>50</sub> (converted to ppm).

ii. The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian or mammalian feed.

12. Required when results of Tier I nontarget organism studies indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects. Additional insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., threatened or endangered species).

13. Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement would be determined by the results of the Tier II environmental fate studies.

14. Required depending on pesticide mode of action, method and timing of application, and results of any available efficacy data. Typically the honeybee acute toxicity guideline (guideline 850.3020) satisfies this requirement, however, additional nontarget insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., endangered species.)

### § 158.2070 Biochemical pesticides product performance data requirements.

Product performance data must be developed for all biochemical pesticides. However, the Agency typically does not require applicants to submit such efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require,

on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

### § 158.2080 Experimental use permit data requirements—biochemical pesticides.

(a) Sections 158.2081 through 158.2084 describe the experimental use permit (EUP) data requirements for biochemical pesticides. Variations in the test conditions are identified within the test notes. Definitions that apply to all biochemical data requirements can be found in § 158.2000.

(b) For general information on the data requirement tables, see § 158.2010(b)-(f).

### § 158.2081 Experimental use permit biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry data requirements for a particular biochemical pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Depending on the results of the required product chemistry studies, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental

use permit biochemical pesticides product chemistry. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Num- ber	Data Requirement	All Use Pat- terns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated tempera- tures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--
830.6319	Miscibility	CR	MP	EP	10
830.6320	Corrosion characteristics	R	MP	EP	--
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11
830.7050	UV/Visible light absorption	R	TGAI	TGAI	--
830.7100	Viscosity	CR	MP	EP	12
830.7200	Melting point/melting range	CR	TGAI	TGAI	8, 13
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16
830.7840	Water solubility	R	TGAI	TGAI	8
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides product

chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with § 158.320.

2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.

3. Data must be provided in accordance with § 158.325, § 158.330, and § 158.335.

4. Data must be provided in accordance with § 158.340.

5. Data must be provided in accordance with § 158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAI) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis. For pesticides in the production stage, a preliminary product analytical method and data would suffice to support an experimental use permit.

6. Data must be provided in accordance with § 158.350.

7. Data must be provided in accordance with § 158.355.

8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.

9. Required if the product contains combustible liquids.

10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

11. Required if the test substance is soluble or dispersible in water.

12. Required if the product is a liquid.

13. Required when the technical chemical is a solid at room temperature.

14. Required when the technical chemical is a liquid at room temperature.

15. Required for water insoluble test substances ( $>10^{-6}$ g/l) and fibrous test substances with diameter  $\geq 0.1$   $\mu$ m.

16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.

17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.

18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.

19. Not required for salts.

**§ 158.2082 Experimental use permit biochemical pesticides residue data requirements table.**

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a par-

ticular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, *i.e.*, naturally occurring insect repellents and attractants, semiochemicals (e.g., insect pheromones), natural and plant growth regulators. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Data are required or conditionally required for all pesticides used in or on food and for residential outdoor uses where food crops are grown. Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use. Data are also conditionally required for aquatic nonfood use if there is direct application to water that could subsequently result in exposure to food.

(2) Data are conditionally required for nonfood uses if pesticide residues may occur in food or feed as a result of the use. Data requirements for these nonfood uses would be determined on a case-by-case basis. For example, most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing end-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern. All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Data table.* The following table shows the data requirements for biochemical pesticides residue. The test notes are shown in paragraph (e) of this section.